RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-7
STERILE PRODUCT PREPARATION IN PHARMACY PRACTICE

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1140-7-.01 APPLICABILITY.

The provisions of this Chapter shall apply to all pharmacy practice sites and pharmacists, pharmacy interns, pharmacy technicians and supportive personnel involved in the compounding and dispensing of sterile products.

***Authority**: T.C.A. § 63-10-404(4),(11),(26),(28),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.02 PERSONNEL.

(1) The pharmacist in charge or pharmacist designee shall be responsible for, at a minimum, the following:

(a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all prescription drugs and devices and related materials necessary in compounding and dispensing sterile products;

(b) Establishment of policies and procedures for the compounding and dispensing of sterile products;

(c) Documentation of competency in aseptic techniques of all pharmacists, pharmacy interns and pharmacy technicians. The aseptic technique of each person compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training and at least on an annual basis or whenever unacceptable techniques are observed or detected;

(d) Establishment of a quality assurance program;

(e) Reviewing and updating annually all policies and procedures; and

(f) Provision of sterile products on a twenty four (24) hour a day basis.

(2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-2-.02 responsible for compounding or dispensing sterile products shall:

(a) Obtain practical and/or academic training in the compounding and dispensing of sterile products;

(b) Complete annual continuing education related to sterile product compounding and dispensing and utilization; and

(Rule 1140-7-.02, continued)

(c) Maintain, in the pharmacy practice site, documentation of completion of the required training and continuing education.

(d) Use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policies and procedures.

(3) A pharmacist shall be available to respond to patients' and other health care practitioners' information needs on a twenty four (24) hour a day basis.

(4) The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-2-.02 and supportive personnel necessary to operate the pharmacy practice site competently and safely and to provide services in a timely and appropriate manner.

(5) All pharmacists, pharmacy interns and pharmacy technicians must be qualified through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such pharmacists, interns and technicians will be assigned to use to compound and dispense sterile products.

(6) A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site and contain the following information:

(a) Name of the person receiving the training or evaluation;
(b) Date(s) of the training or evaluation;
(c) General description of the topics covered; and
(d) Signature of the person receiving the training or evaluation and the pharmacist in charge or pharmacist designee of the pharmacist in charge.

Authority*: T.C.A. § 63-10-404(4),(5),(8),(11),(14),(16),(26),(27),(29),(30), §63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.03 PHYSICAL REQUIREMENTS.

(1) Area, Equipment and Materials.

(a) 1. The sterile product compounding area shall be enclosed from other pharmacy practice site operations in order to minimize the potential for sterile product contamination.

2. This area shall be designed as a limited access area to avoid unnecessary traffic and airflow disturbances.

3. The enclosure of the sterile product compounding area may be achieved through the utilization of partitions, plastic curtains, or similar washable solid surface dividers.

4. Entrances to the sterile product compounding area must contribute to the enclosure.

5. Materials utilized to define the enclosure must extend from the floor to a minimum of the top of the hood.

6. All surfaces of the sterile product compounding area shall be washable, non carpeted, and low particulate generating.

(Rule 1140-7-.03, continued)

7. No new construction or remodeling will be approved that is not either:

(i) Fully enclosed as noted in paragraphs (3), (4) and (5) above; or

(ii) Has documented engineering studies validating that air flow in a partially opened design creates an atmosphere that is equal to a fully enclosed design.

(b) For hand washing a sink with hot and cold running water shall be located in or adjacent to the area where sterile products are compounded.

(c) There shall be appropriate refrigeration for storing supplies and sterile products requiring refrigeration after being prepared and before being dispensed or administered to patients.

1. Documentation of refrigeration integrity shall be maintained in accordance with the pharmacy practice site's policies and procedures.

(d) The storage of prescription drugs and devices and related materials shall be under appropriate conditions (e.g., controlled temperature, well lighted, dry, clean, secure, and well ventilated).

1. Prescription drugs and devices and related materials shall not be stored in the sterile product compounding area in shipping containers (e.g., corrugated cardboard or other high particulate producing containers).

2. After removal from shipping containers, unit packaging will be acceptable for storage in the sterile product compounding area.

(e) All sterile product compounding must be performed within a Class 100 laminar flow hood, biologic-safety cabinet (Class II, Type A) or within a Class 100 clean room.

(f) Laminar flow hoods, biologic safety cabinets (Class II, Type A) and Class 100 clean rooms shall be certified according to current federal standards for operational efficiency at least semi-annually.

(g) The laminar flow hood, biologic safety cabinet (Class II, Type A) or Class 100 clean room shall be kept running continuously; however, if the hood is turned off, the hood shall be functioning at least thirty (30) minutes before being used to compound sterile products, or according to recommendations of the manufacturer to achieve appropriate air velocity and a complete cleaning of the inside works before being used to compound sterile products.

(h) The sterile product compounding area shall be adequately ventilated so as not to interfere with laminar flow hood conditions and be used only for the compounding of sterile products.

(i) Prefilters in laminar flow hoods shall be changed at least quarterly and a written record of such change shall be maintained.

(j) The storage of prescription drugs, devices and related materials outside of the pharmacy shall be supervised and approved by the pharmacist in charge and inspected monthly to ensure that the products' safe storage is being maintained. These inspections shall be in accordance with rule 1140-4-.18.

(Rule 1140-7-.03, continued)

Authority: *T.C.A. § 63-10-404(4),(8),(14), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.04 POLICY AND PROCEDURE MANUAL.

(1) A policy and procedure manual related to sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for:

(a) security;
(b) equipment;
(c) sanitation;
(d) reference materials;
(e) prescription drug and device and related material storage;
(f) prescription drug and device and related material compounding and dispensing;
(g) prescription drug and device and related material labeling and relabeling;
(h) prescription drug and device and related material destruction and returns;
(i) dispensing of sterile products;
(j) record keeping;
(k) quality assurance;
(l) quality control;
(m) duties for pharmacist(s), pharmacy intern(s), pharmacy technician(s) and supportive personnel;
(n) public safety relative to harmful sterile products;
(o) attire; and
(p) pharmacist, pharmacy intern, and pharmacy technician training.

Authority*: T.C.A. § 63-10-404(4),(8),(14),(26),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed November 16, 1992; effective January 8, 1993. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.05 LABELING.

(1) At the time of dispensing of the sterile product, the dispensing container must bear a label which contains the following information:

(a) patient's name (if for outpatient use);
(b) prescriber (s) name (if for outpatient use);
(c) pharmacy practice site name, address, and phone number (if for outpatient use);
(d) identification of the pharmacist who compounded the sterile product;
(e) when applicable, identification of the pharmacy intern or pharmacy technician who assisted in the compounding of the sterile product;
(f) name and amount of drug added;
(g) expiration date and, when applicable, expiration time;
(h) date of compounding;
(i) appropriate auxiliary label(s); and
(j) directions for use (if for outpatient).

(2) Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

Authority*: T.C.A. §63-10-404(11),(14),(19),(26),(28),(29),(30),(32),(34), §63-10-504(b(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.06 HAZARDOUS PRODUCTS.

(1) Physical Requirements.

(a) If the pharmacy practice site is engaged in the compounding of hazardous sterile products, a suitable facility to prepare such products and minimize the risk associated with such products shall be provided.

(b) Such pharmacy practice site shall be designed and equipped for storage and have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

(1) A dedicated Class II, Type A contained vertical flow biohazard cabinet is the minimally acceptable compounding site for the routine compounding of hazardous sterile products.

(2) Hazardous sterile products shall be segregated within the pharmacy practice site and storage areas so identified.

(2) Dispensing.

(a) Prepared doses of hazardous sterile products for patients shall be placed in an appropriate outer wrap to minimize the risk exposure in case of accidental rupture of the primary container.

(b) Reasonable effort shall be made to assure that all hazardous sterile product primary containers and waste are removed from the site of use and disposed of as hazardous waste in accordance with applicable state and federal laws.

(3) Training.

(a) As part of the training for all pharmacists, pharmacy interns and pharmacy technicians involved in compounding of hazardous sterile products, an annual certification must be made by each pharmacist, pharmacy intern and pharmacy technician and the pharmacist in charge that each has read and understands the latest editions of:

1. Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs (Occupational); and

2. The American Society of Health-System Pharmacists (ASHP) technical assistance bulletin on handling cytotoxic and hazardous substances.

(4) Hazardous sterile products dispensed shall bear a distinctive warning label with an appropriate caution statement thereon.

(5) Gloving and gowning shall be required in the compounding of hazardous sterile products. Gloves should be rinsed frequently with a sanitizing agent (e.g., seventy percent (70%) isopropyl alcohol) and shall be changed when the integrity of the gloves is compromised.

(6) In the compounding of hazardous sterile products, a protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs with cuffs tucked under the gloves shall be worn. Gowns and gloves used in the compounding of hazardous sterile products shall not be worn outside the sterile product compounding area.

(Rule 1140-7-.06, continued)

Authority: *T.C.A. § 63-10-404(4),(11),(26),(27),(28),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.07 ATTIRE.

(1) All pharmacists, pharmacy interns and pharmacy technicians shall wear clean garments that generate low levels of particulate. Concerning clothing worn in a sterile product compounding area with a laminar flow hood or biologic safety cabinet (Class II, Type A), one (1) of the following must apply:

(a) Upon entering the sterile product compounding area, pharmacists, pharmacy interns and pharmacy technicians shall don an outer garment that generates a low level of particulate (e.g., clean laboratory jacket, disposable gown) before compounding sterile products. Upon leaving the sterile product compounding area, this outer garment shall be disposed of or left at the entrance of the sterile product compounding area and donned when re-entering the area.

(b) If scrubs or site specific clothing are donned for work in the sterile product compounding area, a laboratory jacket or outer covering shall be worn while outside the sterile product compounding area in order to protect the scrubs or site specific clothing from cross contamination. Upon entering the sterile product compounding area the lab jacket or outer covering shall be removed before compounding sterile products.

(2) All pharmacists, pharmacy interns and pharmacy technicians with respiratory conditions that may result in contamination of sterile products shall wear a mask.

(3) For the compounding of sterile products prior to receipt of specific medical or prescription orders and when the anticipated dispensing time may be greater than twenty eight (28) hours after preparation; clean, low particulate outer garments and gloves shall be required. Hair cover and a mask shall be required, unless a biologic safety cabinet (Class II, Type A) is utilized.

(4) If utilizing a Class 100 clean room without a laminar flow hood, the attire shall include a jumpsuit or surgical scrubs and head coverings that generate low levels of particulate, mask, shoe covers, and gloves.

(5) Attire specific to the compounding of hazardous sterile products is explained in rule 1140-7-.06.

Authority: *T.C.A. § 63-10-404(4),(26),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-7-.08 QUALITY ASSURANCE.

(1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.

(2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality sterile products.

Authority: *T. C.A. § 63-10-404(26),(28),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*